

# BIOWORLD® TODAY

THURSDAY  
JANUARY 20, 2011

THE DAILY BIOTECHNOLOGY NEWSPAPER

VOLUME 22, No. 13  
PAGE 1 OF 7

## Theraclone, Pfizer Ink Antibody Agreement Worth up to \$632M

By Marie Powers  
*BioWorld Today Contributing Writer*

Privately held Theraclone Sciences Inc., of Seattle, has grabbed a tiger by the tail, inking a multiyear research and development collaboration with Pfizer Inc. for the company's in situ therapeutic antibody rescue (I-STAR) technology. The deal makes Theraclone eligible to receive up to \$632 million in research funding and milestone payments upon the achievement of discovery, development, regulatory and commercialization milestones, plus undisclosed royalties on future sales.

New York-based Pfizer will be responsible for preclinical and clinical development of the antibodies.

The companies will use Theraclone's I-STAR technology to discover broadly protective monoclonal antibodies against up to two infectious disease targets and up to two cancer targets. Pfizer will receive an exclusive worldwide

*See Theraclone, Page 3*

*Overall, Progression-Free Survival Benefits*

## Plexxikon BRIMs with Joy over PLX4032 Phase III Data

By Anette Breindl  
*Science Editor*

Melanoma drug PLX4032 has set the cancer world abuzz more than once over the past year and a half. And with an interim analysis of a Phase III trial released yesterday that showed both an overall survival benefit and a progression-free survival benefit for patients taking the drug as a first-line agent, it is doing it again.

The 675-patient BRIM 3 study is the first where PLX4032, which also goes by the name RG7204, was used as a first-line agent for BRAF mutation positive metastatic melanoma. Patients were randomized to receive either oral PLX4032 twice daily, or the current standard of care, which consists of intravenous dacarbazine every three weeks.

Plexxikon CEO Peter Hirth declined to give any more

*See Plexxikon, Page 4*

*FDA Wants More Data*

## MannKind Slides on Second Afrezza Complete Response

By Jennifer Boggs  
*Assistant Managing Editor*

It was just as MannKind Corp.'s bearish investors predicted when the FDA said it was extending the PDUFA date for inhaled insulin candidate Afrezza: The agency issued a complete response letter – the second – for use of the product in Type I and Type II diabetes.

While the first CRL did not specifically require additional clinical data – the agency instead asked for more information on Afrezza's clinical utility and the company's next-generation inhaler device – the second letter requested the firm to conduct two clinical studies using its newer inhaler, one testing the product in Type I diabetics and the other in Type II disease. And at least one of those studies should include a treatment group using the MedTone inhaler from previous trials for a head-to-head comparison. (See *BioWorld*

*See MannKind, Page 5*

*Financings Roundup*

## Nektar Selling 19M Shares as Firm Goes Solo on NKTR-102

By Jennifer Boggs  
*Assistant Managing Editor*

A week after President and CEO Howard W. Robin told investors at the J.P. Morgan Healthcare Conference in San Francisco that Nektar Therapeutics Inc. planned to move into Phase III on its own with cancer drug NKTR-102, the firm priced a hefty public offering to bolster its cash reserves.

San Francisco-based Nektar did not disclose the share price for the 19 million shares. Tuesday's closing price of \$12.34 would put gross proceeds at about \$234.5 million, though shares likely were offered at a discount. Underwriter Jefferies & Co. Inc. has the option of purchasing an additional 2.85 million shares to cover overallotments.

Shares (NASDAQ:NKTR) dropped 90 cents on the

*See Financings Roundup, Page 6*

**INSIDE:**

CLINIC ROUNDUP: BIOMARIN, GERON, GLAXOSMITHKLINE ..... 2  
OTHER NEWS TO NOTE: IRONWOOD, PERVASIS, PROTALIX ..... 7

**AHC Media LLC**

## Clinic Roundup

• **BioMarin Pharmaceutical Inc.**, of Novato, Calif., has initiated a Phase I/II trial for BMN 701, a fusion protein of insulin-like growth factor 2 and acid alpha glucosidase in development for the treatment of Pompe disease. The open-label study will evaluate the safety, tolerability, pharmacokinetics, pharmacodynamic and clinical activity of BMN 701 administered as an intravenous infusion every two weeks at doses of 5 mg/kg, 10 mg/kg and 20 mg/kg. The company expects to enroll approximately 30 patients between the ages of 13 and 65 with late-onset Pompe disease for a treatment period of 24 weeks.

• **Geron Corp.**, of Menlo Park, Calif., announced enrollment of the first patient in a Phase II trial to evaluate the activity of the company's telomerase inhibitor drug, imetelstat (GRN163L), in patients with essential thrombocythemia (ET). ET is a chronic disorder that arises in the hematopoietic stem cells in the bone marrow. The leukemic stem cells produce aberrant clones of platelet-forming cells, which results in increased numbers of circulating platelets. The trial is a Phase II, open-label study of imetelstat as a single agent in patients with ET who have failed or are intolerant to at least one prior therapy or who refuse standard therapy, such as hydroxyurea, anagrelide or interferon-alpha.

• **GlaxoSmithKline plc**, of London, and **Prosensa Therapeutics**, of Leiden, the Netherlands, said the first patient commenced treatment in a Phase III study investigating GSK2402968 in ambulant boys with Duchenne's muscular dystrophy (DMD), who have a dystrophin gene mutation amenable to an exon 51 skip. The randomized, placebo-controlled study will enroll 180 patients, from up to 18 countries. It's designed to assess the efficacy and safety of GSK968 6mg/kg, once weekly, compared to placebo, for 48 weeks in ambulant boys older than 5 years with DMD. The primary efficacy endpoint is a measure of muscle function using the six minute walking distance test.

## Stock Movers

01/19/11

Company	Stock Change	
Nasdaq Biotechnology	-\$23.61	-2.3%
ARIAD Pharmaceuticals Inc.	-\$0.76	-10.9%
Curis Inc.	-\$0.34	-10.9%
Depomed Inc.	-\$0.92	-14.0%
Icagen Inc.	+\$0.67	+29.5%
SciClone Pharmaceuticals Inc.	-\$0.45	-10.3%
Synta Pharmaceuticals Corp.	-\$0.95	-14.7%

(Biotechs showing significant stock changes Wednesday)

## Corrections & Clarifications

A news brief in the Jan. 19, 2011, issue of *BioWorld Today* should have stated that Monosol RX LLC amended a patent infringement and false marking lawsuit against BioDelivery Sciences International Inc., MEDA Pharmaceuticals Inc. and Aveva Drug Delivery Systems Inc.

*Editor's note: The correction has been made in BioWorld Online.*

• **Koronis Pharmaceuticals Inc.**, of Seattle, said Phase IIa trial results showed that the frequency of specific drug-induced mutations in the HIV genome can be significantly increased by administering KP-1461, a drug based on the firm's Viral Decay Acceleration platform. Data were published in the Jan. 14, 2011, issue of *PLoS One*. Koronis is planning a follow-on Phase II trial to determine the treatment duration required to achieve a clinically meaningful decrease in a patient's viral load.

BioWorld® Today (ISSN# 1541-0595) is published every business day by AHC Media, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305 U.S.A. Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. BioWorld® and BioWorld® Today are trademarks of AHC Media, a Thompson Publishing Group company. Copyright © 2011 AHC Media. All Rights Reserved. No part of this publication may be reproduced without the written consent of AHC Media. (GST Registration Number R128870672).

**ATLANTA NEWSROOM:** Managing Editor: **Lynn Yoffee**. Assistant Managing Editor: **Jennifer Boggs**. Senior Staff Writer: **Karen Pihl-Carey**. Senior Production Editor: **Ann Duncan**. Staff Writer: **Tom Wall**.

**WEST COAST BUREAU:** Staff Writer: **Trista Morrison**.

**EAST COAST BUREAU:** Science Editor: **Anette Breindl**.

**BUSINESS OFFICE:** Senior Vice President/Group Publisher: **Donald R. Johnston**. Director of Product Management: **Jane Cazzorla**. Marketing Manager: **Sarah Cross**. Account Representatives: **Matt Hartzog**, **Chris Wiley**, **Scott Robinson**.

**DISPLAY ADVERTISING:** For ad rates and information, please call **Stephen Vance** at (404) 262-5511 or email him at [stephen.vance@ahcmedia.com](mailto:stephen.vance@ahcmedia.com).

**REPRINTS:** For photocopy rights or reprints, call our reprints department at (404) 262-5479.

**PRESS MATERIALS:** Send all press releases and related information to [newsdesk@bioworld.com](mailto:newsdesk@bioworld.com).

### SUBSCRIBER INFORMATION

Please call **(800) 688-2421** to subscribe or if you have fax transmission problems. Outside U.S. and Canada, call **(404) 262-5476**. Our customer service hours are 8:30 a.m. to 6:00 p.m. EST.

Lynn Yoffee, **(404) 262-5408**  
Jennifer Boggs, **(404) 262-5427**  
Anette Breindl, **(518) 595-4041**  
Trista Morrison, **(858) 901-4785**  
Tom Wall, **(404) 262-5417**

Senior Vice President/Group Publisher:  
Donald R. Johnston, **(404) 262-5439**

Internet: <http://www.bioworld.com>

**AHC Media LLC**

## Theraclone

*Continued from page 1*

license to any therapeutic antibodies discovered under the collaboration.

The deal came together through Theraclone's acquaintance with Jose-Carlos Gutiérrez-Ramos, who joined Pfizer last January as senior vice president of worldwide biotherapeutics research and development. Gutiérrez-Ramos had learned of Theraclone's technology during his previous tenure as senior vice president and head of the Immunoinflammation Center for Drug Discovery at GlaxoSmithKline plc, of London. He introduced Theraclone executives to officials in Pfizer's oncology research program, who were equally intrigued with the technology, according to Steve Gillis, Theraclone's interim CEO and managing director of the investment firm ARCH Venture Partners.

In turn, Pfizer's oncology team introduced the I-STAR technology to members of the company's infectious disease group, who also wanted to apply it to targets of interest.

"In today's world, you always need to be talking to potential partners in the endless pursuit of nondilutive funding," Gillis told *BioWorld Today*. "The potential of getting two separate transactions was possible, as was the potential to roll everything into one transaction. At the end of the day, that's what we did."

Pfizer officials did not respond to requests for an interview, but Gutiérrez-Ramos said in a statement, "Theraclone's platform technology represents an important advancement in fully human therapeutic antibody discovery, which we believe has the potential to deliver a new generation of improved therapeutic antibodies more efficiently."

I-STAR technology uses memory B cells taken from blood samples of human donors with natural resistance to a disease of interest, Gillis explained. Each memory B cell has the potential to differentiate and make a unique antibody clone. The company cultures tens of thousands of memory B cells in microtiter wells at a density of one cell per well, then activates these cells to propagate and differentiate into antibody-producing cells. "Our technology wakes up those cells and interrogates them at the single cell level," Gillis said.

Antibodies that are secreted into the culture medium are harvested in sufficient quantity to enable screening for biological activity. Once an antibody with desired activity is found in the screen, the gene sequence for that antibody is obtained from the corresponding antibody-producing cells. The antibody genes then can be inserted into immortalized mammalian cells to enable production of unlimited quantities of that antibody clone for further study.

I-STAR technology enables Theraclone to test the function of tens of thousands of natural human antibodies rapidly and to find those with exceptional biologic activity.

"We've been fortunate in being able to incorporate early in the discovery screening [process] not just binding screens but functional screens and, therefore, we can get a

head start on going after antibodies of interest," Gillis said.

Theraclone also signed a multiyear R&D agreement in October 2009 with Zenyaku Kogyo Co. Ltd., of Tokyo, to use the I-STAR technology to discover broadly protective monoclonal antibodies for pandemic influenza and severe seasonal influenza. Zenyaku holds an option to exclusive antibody rights in Asia, including certain Oceania countries, and retains an option in the territory to potential vaccine candidates stemming from the discovery research. In exchange, Theraclone received an up-front cash payment and is eligible for R&D milestones totaling more than \$18 million through Phase I, plus additional milestones and royalties on future sales.

In June 2010, Theraclone researchers published data in *Proceedings of the National Academy of Sciences* indicating they had discovered a highly conserved molecular target on the influenza A virus and demonstrated in preclinical studies that antibodies against the target provide protection against seasonal and avian influenza. Theraclone researchers also participated in a study led by the International AIDS Vaccine Initiative that described two broadly neutralizing antibodies to HIV and a strategy to discover more of them. The results were published in the Sept 4, 2009, issue of *Science*. (See *BioWorld Today*, Sept. 4, 2009.)

In 2008, Theraclone was granted an award under IAVI's Innovation Fund to test its process for isolating from the blood of certain HIV-infected individuals potent monoclonal antibodies to HIV that are broadly neutralizing.

Unlike some other antibody discovery platforms, "we've demonstrated over the past couple of years the ability to generate antibodies," Gillis said. "Our publications in HIV and influenza have certainly helped validate the technology platform. We really believe we can interrogate every B cell in the human repertoire and, in doing so, find very rare antibodies that are broadly neutralizing and very, very potent. Therein lies the strength of the platform.

"We're taking an influenza antibody into the clinic in the middle of the year and hope to follow with a [cytomegalovirus] antibody at the end of the year," he added, noting that several other in-house discovery programs are under way.

Theraclone (formerly Spaltudaq Corp.) was founded in November 2004 as the third start-up of the biotech investment firm Accelerator Corp., of Seattle. Currently, the company has about 20 full-time employees, but head count will increase to meet the obligations of the Pfizer collaboration, according to Gillis.

The company's most recent financing – a Series B that pulled in \$29 million – took place in 2007, co-led by ARCH Venture Partners, Canaan Partners and Healthcare Ventures, with participation from Amgen Ventures, MPM Capital and Alexandria Equities LLC. At this time, Theraclone has no plans to go public, Gillis said, noting that "the public markets certainly haven't shown themselves to be receptive to development-stage companies." ■

## Plexxikon

*Continued from page 1*

details about the magnitude of either survival benefit, or the response rate. But, he told *BioWorld Today*, the data were so strong that the study was terminated early, and patients in the control arm have been given the option to cross over onto PLX4032. In that sense, he said, “the study is done,” because trying to gauge differences once there is such a crossover option “would lead the overall survival [measurements] ad absurdum.

“However,” he added, “we are still following the patients from a safety perspective.”

Based on the data, the company plans to file for regulatory approval for PLX4032 in 2011, Plexxikon President Kathy Glaub told *BioWorld Today*.

With that, the company may just be breaking a land speed record. The Phase I trial of PLX4032 began in mid-2009. The results of that trial, which were published in 2010, prompted the drug’s developers, Berkeley, Calif.-based Plexxikon and partner Roche AG, to move the drug directly into pivotal testing. The first patient was enrolled in the BRIM3 study in January 2010.

“We will probably see more of this [rapid clinical progress] with other personalized drugs,” Glaub said. PLX4032, she added, is “a highly personalized drug and as a result, we’re really forging some new pathways, even in the regulatory area.”

PLX4032, an orally active kinase inhibitor that targets an activating BRAF mutation, is also an example of the power of personalized medicine. The drug is being co-developed with a diagnostic test to identify patients whose tumors carry the V600 mutation. Such mutations account for about half of all melanoma cases.

The extremely rapid hurtle down the clinical development path also means that the conclusions about PLX4032’s safety and efficacy are based on relatively few patients, and relatively few clinical events. Such small numbers and statistics can be shaky, but both Hirth and Glaub said that because of the strength of the data, they are not concerned that the sample size is small.

“We’re not worried, because we’ve seen such consistent data that it has really been very clear,” Glaub said. And because PLX4032 is undergoing “a very exceptional development paradigm,” which was characterized from the beginning by testing the drug only in a molecularly targeted population, the trials were designed to get a lot of information. “In a way, our Phase I trial produced data that are usually what you get in Phase II.”

Finally, Hirth added, “the more impact a drug has, the easier it is to see [effects]. . . . This is all a testament to the power of the drug.”

With response rates of up to 80 percent reported in early stage trials, PLX4032 is something of a wonder drug in the cancer field, where drugs can be approved and considered successes with response rates of well below 25 percent.

But there had been concern that even such stellar response rates might not translate into improved survival.

Drug developers and patients alike have been disappointed before – targeted cancer drug Iressa (gefitinib, AstraZeneca plc), for example, received fast-track approval in 2003 on the basis of response rate, but subsequently its indications were severely curtailed when a Phase IV study failed to show a survival benefit for patients taking the drug. (See *BioWorld Today*, May 6, 2003, and Dec. 20, 2004.)

At 10 percent, the response rate to Iressa was far lower than that to PLX4032. But worries about survival were also fueled by another statistic about PLX4032: More than half of the patients in one trial developed resistance to the drug within less than a year, apparently via a multitude of mechanisms. (See *BioWorld Today*, Nov. 29, 2010.)

The increase in overall and progression-free survival, which were the co-primary endpoints of the BRIM3 trial, lay those worries to rest.

Hirth said that precisely because the BRIM3 trial ended so quickly, the interim analysis doesn’t have any information about resistance yet. “In that early readout, we would not see anything” that could tell the company what the long-term resistance rate might be.

But, he added, “we have been actively working on [resistance] . . . and we think we’ve had a major breakthrough. We are working on a best-in-class agent that will hopefully not have this resistance issue.” The company also plans to share more details about that scientific advance at a medical conference in 2011. ■

## Clinic Roundup

• **Merck Serono**, a division of Merck KGaA, of Darmstadt, Germany, reported further analysis of the large, randomized Phase II OPUSa study demonstrating an association between early tumor shrinkage and long-term median overall survival of more than two years for patients with KRAS wild-type metastatic colorectal cancer treated with Erbitux (cetuximab) plus Folfex standard chemotherapy. The correlation was not seen in the chemotherapy-alone arm of the study. The study will be presented at the annual Gastrointestinal Cancers Symposium of the American Society of Clinical Oncology.

• **Peregrine Pharmaceuticals Inc.**, of Tustin, Calif., and Tucson, Ariz., initiated an investigator-sponsored trial for patients with HER2-negative metastatic breast cancer, which accounts for 75 percent of metastatic breast cancers. The open-label Phase I study will treat patients with Peregrine’s investigational monoclonal antibody bavituximab in combination with the chemotherapy agent paclitaxel. Currently, Peregrine’s bavituximab is being evaluated in randomized Phase II trials in front-line non-small-cell lung cancer (NSCLC), second-line NSCLC, pancreatic cancer and hepatitis C.

## MannKind

*Continued from page 1*

Today, March 16, 2010.)

Shares of MannKind (NASDAQ:MNK) fell 72 cents Wednesday to close at \$9.11.

The good news is that the Valencia, Calif.-based firm already has started two trials testing the new device. AFFINITY 1 is enrolling Type I diabetes patients, while AFFINITY 2 is enrolling Type II diabetics. "We plan to meet with the agency as quickly as possible in order to be confident that these trials, with appropriate modifications to incorporate a comparison to the MedTone device, will suffice in addressing the agency's questions," Alfred Mann, chairman and CEO, said in a statement.

He stressed that the FDA was asking only for data to confirm the bridging and handling of the new device.

MannKind had hoped to gain approval of Afrezza last year, with plans to submit a supplemental application after completing trials with the next-generation inhaler. That newer inhaler could be key to market uptake of the product.

Inhaled insulin has remained a shaky proposition following Exubera, which gained approval only to be pulled from the market by Pfizer Inc. and Nektar Therapeutics Inc.

after dismal sales. A bulky and inconvenient inhaler was partly to blame. (See *BioWorld Today*, April 10, 2008.)

MannKind has soldiered on, even as other competitors backed away from inhaled insulin programs.

Partners Novo Nordisk A/S and Aradigm Corp. and partners Alkermes Inc. and Eli Lilly and Co. both dropped their respective late-stage programs in the wake of Exubera's demise.

A new player, however, recently emerged. Dance Pharma partnered with Aerogen Ltd. last week to develop an inhaled insulin product using Aerogen's OnQ aerosol generator technology.

The timeline for MannKind resubmitting a new drug application for Afrezza was not immediately clear. But the delay is almost certain to further hold up any partnering discussions.

Fourth-quarter financial results have not yet been released, but MannKind ended the third quarter with about \$98 million in cash.

In addition to the clinical data, the FDA's letter also requested more information, including usage, handling, shipment and storage of the inhaler, plus updated safety information for Afrezza. ■

## Clinic Roundup

- **Pluristem Therapeutics Inc.**, of Haifa, Israel, completed a parallel scientific advisory process with the European Medical Agencies (EMA) and the FDA regarding the company's planned clinical development program for PLX-PAD. Based on positive feedback from the agencies, Pluristem said it is now in a position to advance toward two clinical studies with its PLX-PAD cells: a joint FDA-EMA Phase II/III study of PLX-PAD for critical limb ischemia and a Phase II study for intermittent claudication under the FDA and the Paul Ehrlich Institute, the German competent authority in the European Union. The primary endpoint of the study will be major amputation-free survival rate (amputations and death) at 12 months from the initial treatment with PLX-PAD or placebo.

- **Targacept Inc.**, of Winston-Salem, N.C., reported positive top-line results from a Phase II proof-of-concept trial to assess TC-5619 as an augmentation therapy to improve cognition in patients with schizophrenia. In the trial, TC-5619 met the protocol criteria for a positive result on the primary efficacy outcome measure, the Groton Maze Learning Task of the CogState Schizophrenia Battery, and was well tolerated. Analyses of the full dataset from the trial are ongoing. Based on the outcome of the trial, **AstraZeneca plc**, of London, has the right to license TC-5619 on terms specified in the parties' December 2005 collaboration agreement focused in cognitive disorders including schizophrenia. If AstraZeneca exercises its right to license TC-5619, the agreement provides for AstraZeneca

to make a \$30 million payment to Targacept and to assume responsibility for and fund all future development and commercialization. In that event, Targacept would be eligible to receive additional payments of up to \$212 million, contingent on the achievement of development, regulatory, first commercial sale and first detail milestone events for three indications, as well as stepped double-digit royalties on any future TC-5619 product sales. AstraZeneca said it will decide whether to exercise its license right in the first half of 2011.

## Other News To Note

- **Adventrx Pharmaceuticals Inc.**, of San Diego, said the FDA has established a PDUFA date of Sept. 1 for its review of the Exelbine (ANX-530) new drug application. Adventrx is seeking approval of Exelbine for the same indications as Navelbine, a branded formulation of vinorelbine, including non-small-cell lung cancer.

- **Boehringer Ingelheim GmbH**, of Ingelheim, Germany, will acquire the rights in and substantially all assets at **Amgen Inc.**'s, Fremont, Calif., development and manufacturing facility. The purchase price was not disclosed. The transaction has been approved by the board of directors of each company and is expected to close in March. The plant's 360 employees will join Boehringer Ingelheim, which is a contract manufacturer for Thousand Oaks, Calif.-based Amgen. Amgen, which obtained the Fremont facility through its 2006 acquisition of Abgenix, will continue to operate its South San Francisco facility.

## Financings Roundup

*Continued from page 1*

dilution, closing Wednesday at \$11.43.

Nektar had plenty of cash before this week's financing – Robin told J.P. Morgan attendees that the firm ended 2010 with about \$316 million on its balance sheet – but the additional funds will come in handy when the mid-sized biotech launches a large Phase III program for NKTR-102, a topoisomerase I inhibitor-polymer conjugate. Planning is under way for an 800-patient study in metastatic breast cancer, slated to start in the fourth quarter of this year.

Analysts had been expecting a partnership for NKTR-102, particularly after the firm reported promising data at last year's American Society of Clinical Oncology meeting. And just last month at the San Antonio Breast Cancer Symposium, Nektar disclosed additional Phase II breast cancer data showing that the drug produced an overall response rate of 32 percent when given as a single agent.

Instead, Nektar has chosen, at least for now, to keep the drug for itself. In addition to breast cancer, NKTR-102 also has shown promise in ovarian cancer and colorectal cancer.

Two other late-stage programs are being advanced by partners. Nektar picked up a \$125 million up-front payment in a 2009 deal with AstraZeneca plc, in which the London-based pharma firm gained rights to NKTR-118, an oral peripheral opioid antagonist expected to begin Phase III testing this quarter in opioid-induced constipation, as well as NKTR-119, an early stage R&D program that combines various opioids with NKTR-118. (See *BioWorld Today*, Sept. 22, 2009.)

NKTR-061, an anti-infective drug partnered with Berlin-based Bayer AG, also is set to move into Phase III trials this year. That program is targeting Gram-negative pneumonias, including hospital-acquired, health care-associated and ventilator-associated pneumonias.

On its own, Nektar has several early clinical and preclinical programs, including NKTR-0181, a mu-opioid analgesic candidate expected to begin clinical testing this year.

Proceeds from the latest financing, expected to close Jan. 24, are being raised to support general corporate purposes, including R&D costs, working capital, repaying or repurchasing debt, funding acquisitions or conducting share repurchases.

In other financings news:

- **Oxigene Inc.**, of South San Francisco, entered warrant exchange agreements with each of the holders of outstanding warrants issued March 2010. The agreements are expected to simplify the company's balance sheet and help it regain compliance with Nasdaq listing standards. Shares of Oxigene (NASDAQ:OXGN) closed Wednesday at 22 cents, down 2 cents.

- **Pharmasset Inc.**, of Princeton, N.J., plans to sell 3 million shares of common stock in a public offering.

Pharmasset is offering 2 million shares, with selling stockholders offering about 1 million shares. Underwriters will have a 30-day option to purchase an additional 450,000 shares to cover any overallotments. Net proceeds are expected to support general corporate purposes, including clinical trials, in-licensing or M&A activities. Citi is serving as sole book-running manager, while Morgan Stanley is acting as co-lead manager. Shares of Pharmasset (NASDAQ:VRUS) closed Wednesday at \$46.48, down \$3.53.

- **pSivida Corp.**, of Watertown, Mass., is raising gross proceeds of \$10.75 million in a registered direct offering of about 2.15 million shares and warrants to purchase 537,500 shares of common stock. Net proceeds, which are expected to total about \$9.9 million, will go toward general corporate purposes. pSivida develops sustained-release drug delivery products, including Iluvien (fluocinolone acetonide intravitreal insert) for diabetic macular edema. Iluvien, partnered with **Alimera Sciences Inc.**, of Atlanta, received a complete response letter in December. Shares of pSivida (NASDAQ:PSDV) fell 6 cents Wednesday to close at \$4.85. (See *BioWorld Today*, Dec. 28, 2010.) ■

## Other News To Note

- **Collectis SA**, of Paris, said its scientists, working in collaboration with the French National Center For Medical Research and the Institut de la Vision in Paris, used its meganucleases to prevent infection of cultured cells by a herpes simplex virus (HSV-1). Subsequent analysis of the treated cells showed that inhibition of HSV-1 infection by the anti-HSV-1 meganucleases was associated with cleavage of viral DNA. The research, published online in *Molecular Therapy*, offered the first proof-of-concept data showing that meganucleases can prevent viral infection, according to the company.

- **Depomed Inc.**, of Menlo Park, Calif., and Abbott Products Inc. agreed to mediate their dispute over the commercialization of DM-1796, an investigational, once-daily formulation of gabapentin for the management of post-herpetic neuralgia – the type of pain that follows a bout of shingles. **Abbott**, of Abbott Park, Ill., recently informed Depomed that it does not consider itself obligated to launch and commercialize DM-1796, which was developed by Depomed and is licensed to Abbott Products in the U.S., Canada and Mexico for the treatment of pain. Depomed entered into the DM-1796 license agreement with Solvay Pharmaceuticals in November 2008. Abbott Products assumed the license agreement as a result of the acquisition of Solvay's pharmaceutical business by Abbott. The DM-1796 new drug application is under review by the FDA with a PDUFA date of Jan. 30. (See *BioWorld Today*, April 1, 2010.)

## Other News To Note

• **Ironwood Pharmaceuticals Inc.**, of Cambridge, Mass., and **Protagonist Therapeutics Inc.**, of Redwood City, Calif., established a peptide drug discovery and development collaboration. Protagonist will use its disulfide rich peptide technology platform to design peptides against targets identified by Ironwood, which gains the right to advance such peptides through preclinical and clinical development and onto commercialization. Ironwood made an undisclosed up-front payment to Protagonist and will fund full-time equivalents for Protagonist's drug discovery activities during the collaboration period. Ironwood also will make milestone payments and pay royalties on sales of each product incorporating peptides identified by Protagonist, subject to achieving development and commercialization milestones.

• **Pervasis Therapeutics Inc.**, of Cambridge, Mass., said it is pursuing a matrix-embedded endothelial cell-based therapy (PVS-30200) to target and regulate cell stroma in order to prevent key processes that play a role in advancing solid tumor growth and metastasis. The firm entered an exclusive patent license agreement with the Massachusetts Institute of Technology for all discovery and development activities associated with cellular implants

for cancer diagnosis, prognosis and treatment.

• **Protalix BioTherapeutics Inc.**, of Carmiel, Israel, presented preclinical data showing that PRX-102, its modified alpha-Galactosidase-A (alpha-GAL-A) for the treatment of Fabry disease, demonstrated preliminary efficacy in a Fabry animal model. Chemical modifications to the enzyme resulted in improved activity and enhanced bioavailability. Protalix plans to submit an investigational new drug application for the compound this year. In an in-vitro model of the stomach and intestines, the company's oral glucocerebrosidase (GCD) enzyme – a naturally encapsulated plant cell-expressed form of GCD for the treatment of Gaucher's disease – also demonstrated stability in the cell and protective capacity against degradation in the digestive tract. Rats fed with lyophilized carrot cells expressing GCD also accumulated the active enzyme in target organs – the spleen and liver. Protalix has a \$115 million profit-sharing deal with New York-based **Pfizer Inc.** for its Gaucher's disease drug Uplyso (taliglucerase alfa). (See *BioWorld Today*, Dec. 2, 2009.)

**BioWorld is now on Twitter!**

**Stay Connected, Follow Us on Twitter!**

[www.twitter.com/bioworld](http://www.twitter.com/bioworld)

BIOWORLD®

*Tipping the Market Scales* with Biotech Regimens

# OBESITY REPORT

This brand new market report from *BioWorld Today* shows how a burgeoning disease, a strong public awareness, committed government endeavors and a lack of new drug and device approvals have created the perfect "unmet need" recipe for opportunity. Co-published with *Medical Device Daily*, the report's comprehensive analysis and data, combined with our in-depth forecasts, make this the only source you'll need focusing on the obesity space.

Order this new report today from *BioWorld*— it's just \$299 plus \$17.95 in S&H.



**Call**

1-800-688-2421 or 1-404-262-5476



**Visit**

[www.bioworld.com/bioobesity](http://www.bioworld.com/bioobesity)

**KEY TOPICS COVERED IN THIS 130-PAGE REPORT INCLUDE:**

- The projected revenue growth in pharma and biotech obesity sectors
- Up-to-date news on competitors— R&D, deals and corporate financial activity
- Obesity's contribution to heart disease, cancer, diabetes, stroke, arthritis and more
- Defining obesity as a disease, an epidemic, or just an out-of-control condition
- Childhood obesity probability indicators and statistics for unborn-to-teenage population
- *And much more!*